REMARKS

Claims 2, 6, 12, 20 and 23 are pending after the cancellation of claims 15, 16 and 18. Support for the amendment to the specification and the amendments to claim 2 is found in the specification at page 12, lines 21-25 and in *In re Lundak*. Support for the amendments of claims 6, 12 and 20 are found in those claims as filed and in the specification. Support for new claims 24-26 are in claims 3-5 as filed. No new matter is believed to be presented. Entry and consideration of the amendments and allowance of the claims are respectfully requested.

Reference to Related Applications

For the Examiner's information, the following table lists related applications and patents:

Client Matter No.	Application Number	Filing Date	Patent	Patent Grant Date
14114.0300P1	PCT/US99/13421	11JE1999		
14114.0300U2	10/168602	11JE1999		
14114.0311U1	07/791377	17SE1991	5422427	06JE1995
14114.0311U2	08/356106	17SE1991	6312944	06NO2001
14114.0311U3	08/715131	17SE1991	5854416	17SE1991
14114.0311U4	09/221753	17SE1991	6217884	17AP2001
14114.0311U5	09/754809	17SE1991		
14114.0311U6	10/455109	17SE1991		
14114.0341U1	09/613092	10JL2000	6903184	7JE2005
14114.0380U1	60/682495	19MY2005		
14114.0381U2	09/600057	14JA1999		

Deposit of Monoclonal Antibody 1B6E12H9

Claim 2 is rejected as allegedly lacking enablement because the recited antibody was not deposited (paragraph 14 of the office action).

A deposit of a hybridoma producing monoclonal antibody 1B6E12H9 has been made. The specification is amended to add the deposit and depository information. Claim 2 is amended to recite the ATCC deposit number (supported as provided in *In re* Lundak). The required

statements are provided below.

A deposit has been made and accepted by an International Depository Authority under the provisions of the Budapest Treaty. All restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and the deposit will be replaced if viable samples cannot be dispensed by the depository is required.

The specification has been amended to recite the date of the deposit and the complete name and address of the depository.

Also, because the deposit was made after the time of filing, a Declaration of Dr. Jacqueline Sampson Under 37 C.F.R. 1.132 (Exhibit A) is submitted to comply with the requirement to establish a chain of custody. The declaration, executed by a person in a position to know, 1) identifies the deposited hybridoma by its depository accession number, 2) establishes that the deposited hybridoma is the same as that described in the specification, and 3) establishes that the deposited hybridoma was in applicant's possession at the time of filing.

Double Patenting

Claims 12 and 20 are provisionally rejected over claim 11 of application number 09/613,092. Applicants acknowledge this rejection. However, since there is no allowed claim in the present application, and all of the claims under examination are amended herein or are new, the issue of possible double patenting cannot be definitively known at this point. Thus, applicants reserve the right to file a Terminal Disclaimer when a claim is allowed.

Rejections under 35 U.S.C. § 112, First Paragraph (New Matter)

Claim 6 is rejected as containing subject matter which was not described in the specification in such a way as to convey possession of the invention at the time of filing. The

new limitation "consecutive amino acids of SEQ ID NO:6" has been deleted from claim 6 along with any reference to fragments. Thus, this rejection is believed to be overcome, and its withdrawal is respectfully requested.

Claims 12 and 20 are rejected due to the language "one or more peptides ... the peptides..." This language has been deleted from these claims. Thus, this rejection is believed to be overcome, and its withdrawal is respectfully requested.

Rejection under 35 U.S.C. § 112, First Paragraph (Written Description)

Claim 15 is rejected as allegedly lacking written description. This claims is canceled, thus mooting the present rejection.

Rejection under 35 U.S.C. § 112, First Paragraph (Scope of Enablement)

Claims 12, 15, 16, 18 and 20 are rejected as allegedly lacking enablement for a "therapeutic" composition. Claims 15, 16 and 18 are canceled, thus mooting this rejection as to those claims.

Claims 12 and 20 have been amended to delete the term "therapeutic." The office action states that the "enabling disclosure in the instant specification is limited to a purified peptide of SEQ ID NO:6 and a composition comprising the same." Thus, the present amendment to claims 12 and 20 are believed to overcome this rejection, and its withdrawal is respectfully requested.

Rejections under 35 U.S.C. § 112, Second Paragraph

(a) Claim 2 is rejected as indefinite due to the missing accession number and the reference to monoclonal antibody 1B6E12H9. The claim has been amended to recite the ATCC accession number and to refer to the monoclonal antibody "produced by hybridoma 1B6E12H9." Thus, this rejection is believed to be overcome and its withdrawal is respectfully requested.

(b) Claim 6 is rejected as indefinite due to the manner in which claim 2 is referred to. The Examiner's suggestion to amend the claim has been taken. Thus, this rejection is believed to be overcome and its withdrawal is respectfully requested.

(c) The cancellation of claims 16 and 18 renders this rejection moot.

(d) Claim 6 is rejected as indefinite due to the language "immunogenic against *S. pneumoniae.*" This language has been canceled from claim 6. Thus, this rejection is believed to be overcome and its withdrawal is respectfully requested.

(e) The cancellation of claims 16 and 18 renders this rejection moot.

(f) Claims 12 and 20 are rejected as indefinite due to the language "the peptides comprising the amino acid sequence of SEQ ID NO:6." This language has been canceled from claims 12 and 20, and the claims now recite "a peptide comprising the amino acid sequence of SEQ ID NO:6." The language of amended claims 12 and 20 is standard claiming language for peptides and is believed to have a clear and definite meaning in the art. In the absence of evidence to the contrary, this rejection is believed to be overcome and its withdrawal is respectfully requested.

(g) Claim 23 is rejected as indefinite due to the lack of an article before "monoclonal antibody." The amendment of claim 23 to add "a" is believed to overcome this rejection.

(h) Claims 6, 16 and 18, which depend from either claim 2 or 15, are rejected as indefinite because of the indefiniteness of the base claim. Claims 16 and 18 are canceled, thus mooting the rejection of those claims. Claim 2, is amended to address the above rejection. Thus, this rejection of claim 6 is believed to be overcome and its withdrawal is respectfully requested.

Rejections Under 35 U.S.C. § 102

Sampson et al. (6,217,884)

Claim 2 was previously rejected over Sampson et al. and that rejection is maintained in the present office action.

Claim 2 is directed to a purified peptide that immunospecifically binds to the monoclonal antibody designated 1B6E12H9 and deposited with the ATCC. Sampson et al. recites only the laboratory designation for a monoclonal antibody. Based on the proper analysis with regard to enablement of monoclonal antibodies (articulated in the present and previous office actions), antibody 1B6E12H9 was not sufficiently disclosed to have been enabled in the 6,217,884 patent. Sampson et al. shows that the full-length PsaA binds to the antibodies for which they provide laboratory designations, and does not show that any purified peptide binds to any antibody mentioned. Because the antibody was not enabled in Sampson et al., a peptide that immunospecifically binds the antibody, which is not otherwise enabled cannot be enabled in that reference. Since a reference must enable an invention to anticipate it, Sampson et al. does not anticipate claim 2. Thus, withdrawal of this rejection of claim 2 is merited and is respectfully requested.

New claims 24 -26 recite the peptide of claim 2 with specific size limitations as supported in original claims 3-5, and the specification at page 19, lines 10-13. For the reasons indicated above, no such peptide is anticipated in Sampson et al.

Claims 6, 12, 15, 16, 18, 20 and 23 are rejected as allegedly anticipated by Sampson et al. patent 6,217,884 as evidenced by Jarecki-Black (US 6, 368,603). Claims 15, 16 and 18 are canceled, thus mooting this rejection as to those claims.

Claim 6 is amended to delete reference to fragments, while neither claim 12 nor claim 13 ever recited fragments or variants. Claims 6, 12 and 20, thus, do not read on any PsaA fragment that may have been disclosed in Sampson et al.

Furthermore, Sampson et al. does not disclose any peptide, polypeptide or protein comprising the amino acid sequence of SEQ ID NO:6. The office action states that the purified prior art PsaA peptide has to necessarily have the structure of SEQ ID NO:6. The office action does not qualify the term "structure" in any way. Regardless, it is clear from a review of the sequence of PsaA in Sampson et al. that no amino acid sequence exists in the disclosed PsaA protein that comprises the sequence of SEQ ID NO:6. Furthermore, no fragment of PsaA comprises the sequence of SEQ ID NO:6. Claims 6, 12 and 20 recite a peptide comprising the amino acid sequence of SEQ ID NO:6. No reference that fails to disclose the entire sequence of SEQ ID NO:6 can teach a peptide that comprises SEQ ID NO:6. Thus, as written, none of these claims reads on any peptide, polypeptide or protein disclosed in Sampson et al. Sampson et al., therefore, does not anticipate any of claims 6, 12 or 20, such that withdrawal of this rejection is believed to be merited and is respectfully requested.

Claim 23 is directed to a peptide that immunospecifically binds to a monoclonal antibody that binds the peptide of SEQ ID NO:6. No peptide disclosed in Sampson et al. has the sequence of SEQ ID NO:6. Thus, there is no teaching in Sampson et al. of any monoclonal antibody that binds SEQ ID NO:6. Furthermore, Sampson et al. recites only the laboratory designation 1B6E12H9 for a monoclonal antibody. Based on the proper analysis with regard to enablement of monoclonal antibodies (articulated in the present and previous office actions), antibody 1B6E12H9 was not sufficiently disclosed and cannot have been enabled in the 6,217,884 patent.

Since a reference must enable an invention to anticipate it, Sampson et al. does not anticipate claim 23. Thus, withdrawal of this rejection of claim 23 is merited and is respectfully requested.

Nuijens et al.

Claims 2, 6 and 23 are rejected as allegedly anticipated by Nuijens et al. As stated in the office action, this reference discloses a purified peptide that comprises SYQHDL, which is identical to the SYQHDL sequence within SEQ ID NO:6.

Claims 2 and 23 are directed to peptides that immunospecifically bind monoclonal antibody 1B6E12H9, enabled by its deposit with the ATCC. It is clear that there was no enabling disclosure of monoclonal antibody 1B6E12H9 in the art. It is also clear that there is only a 6 amino acid overlap between the 15 amino acid peptide of SEQ ID NO:6 and the 12 amino acid peptide disclosed in Nuijens et al.. The Patent Office in this and the previous office actions has taken the position that neither a fragment of SEQ ID NO:6 (e.g., the 6-mer of Nuijens et al.) nor a peptide with 90% similarity to SEQ ID NO:6 were enabled, *inter alia*, due to lack of predictability of function of fragments or variants of SEQ ID NO:6. Yet, the present office action treats the disclosure in Nuijens et al. of an even more divergent 12-mer peptide having a fragmentary overlap with SEQ ID NO:6 as anticipatory of immunospecific binding with an antibody that was not disclosed in the art. In order for a reference to anticipate an invention, the reference must enable the invention. There is no evidence in Nuijens et al. that enables immunospecific binding with the monoclonal antibody recited in claims 2 and 23. The fact that there is an area of exact overlap between the exemplified peptide and the prior art peptide, which are otherwise significantly different, does not support a conclusion that the prior art peptide possesses the binding characteristic that define claim 2. In fact the 6-amino acid overlap

constitutes only about 40% similarity with SEQ ID NO:6. By the Office's own reasoning, this is not sufficient to enable the recited immunospecifically binding peptide. In contrast, by enabling the recited monoclonal antibody, applicants enable the immunospecifically binding peptides. Since the art must enable the invention in order to anticipate it, this rejection of claims 2 and 23 should fail.

The fact that Nuijens et al. is silent on the issue of binding is crucial, as the absence of such evidence means that the reference does not explicitly teach the invention. There is no evidence or even suggestion in Nuijens et al. that their peptide would immunospecifically bind monoclonal antibody 1B6E12H9. For a peptide that is only 40% related, by the Offices own reasoning there is no basis to assert that binding would be similar. Such an assertion is also inconsistent and nonsensical in view of the Office's application of the enablement standard. Thus, the burden shifting referred to on page 33 is not justified. If the Office is trying to make an inherency rejection, a key requirement of inherency is missing, i.e., that the claimed invention was necessarily practiced in the prior art. Such a rejection cannot be based on a reasonable or statistical likelihood that the claimed composition was present. There is no such certainty in the Nuijens et al. reference even when read in retrospect with the knowledge of the present invention. Thus, there is no credible scientific support for a conclusion that Nuijens et al. either teaches the peptides of claims 2 and 23 or inherently anticipates them.

Claim 6 as amended recites a peptide comprising the amino acid sequence of SEQ ID NO:6. Since there is no peptide in Nuijens et al. that comprises SEQ ID NO:6, this reference does not anticipate claim 6.

Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

No additional fee is believed due. However, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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Gwendolyn D. Spratt — Date: 7-19-05